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Proposed Maximum Residue Limit

PMRL2016-38

Pyrimethanil

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Under the authority of the *Pest Control Products Act*, Health Canada's Pest Management Regulatory Agency (PMRA) has concluded that the addition of new uses on greenhouse cucumbers to the product label of SCALA[®] SC Greenhouse Fungicide, containing technical grade pyrimethanil, is acceptable. The specific uses approved in Canada are detailed on the label of SCALA[®] SC Greenhouse Fungicide, *Pest Control Products Act* Registration Number 29975.

The evaluation of this pyrimethanil application indicated that the end-use product has value and the human health and environmental risks associated with the new uses are acceptable.

Before registering a pesticide for food use in Canada, the PMRA must determine the quantity of residues that are likely to remain in or on the food when the pesticide is used according to label directions and that such residues will not be a concern to human health. This quantity is then legally established as a maximum residue limit (MRL). An MRL applies to the identified raw agricultural food commodity as well as to any processed food product that contains it, except where separate MRLs are specified for the raw agricultural commodity and a processed product made from it.

In addition, the PMRA is proposing to establish MRLs for pyrimethanil on crops included in the Citrus Fruits Group (Revised; Crop Group 10) to permit the import and sale of food containing such residues. The PMRA has determined the quantity of residues that are likely to remain in or on the imported commodities when pyrimethanil is used according to label directions in the exporting country, and that such residues will not be a concern to human health.

Consultation on the proposed MRLs for pyrimethanil is being conducted via this document (see Next Steps, the last section of this document). A summary of the trial data used to support the proposed MRLs can be found in Appendix I.

To comply with Canada's international trade obligations, consultation on the proposed MRLs is also being conducted internationally by notifying the World Trade Organization, as coordinated by the Canada's Notification Authority and Enquiry Point.

The proposed MRLs, to be added to the MRLs already established for pyrimethanil, are as follows.

Table 1 Proposed Maximum Residue Limits for Pyrimethanil

Common Name	Residue Definition	MRL (ppm) ¹	Food Commodity
Pyrimethanil	4,6-dimethyl- <i>N</i> -phenyl-2-pyrimidinamine	10	Citrus fruits (Crop Group 10-Revised) ²
		1.5	Cucumbers

¹ ppm = parts per million

² An MRL of 10 ppm is already established for calamondins, citrus citrons, citrus hybrids, grapefruits, kumquats, lemons, limes, oranges, pummelos, Satsuma mandarins, and tangerines. The 10 ppm MRL is proposed for the remaining commodities in Crop Group 10-Revised.

MRLs are proposed for each commodity included in the listed crop groupings in accordance with the Residue Chemistry Crop Groups webpage in the Pesticides and Pest Management section of Health Canada's website.

MRLs established in Canada may be found using the Maximum Residue Limit Database on the Maximum Residue Limits for Pesticides webpage. The database allows users to search for established MRLs, regulated under the *Pest Control Products Act*, both for pesticides or for food commodities.

International Situation and Trade Implications

MRLs may vary from one country to another for a number of reasons, including differences in pesticide use patterns and the locations of the crop field trials used to generate residue chemistry data.

Table 2 compares the MRLs proposed for pyrimethanil in Canada with corresponding American tolerances and Codex MRLs.¹ American tolerances are listed in the Electronic Code of Federal Regulations, 40 CFR Part 180, by pesticide. A listing of established Codex MRLs is available on the Codex Alimentarius Pesticide Residues in Food website, by pesticide or commodity.

Table 2 Comparison of Canadian MRLs, American Tolerances and Codex MRLs

Food Commodity	Canadian MRL (ppm)	American Tolerance (ppm)	Codex MRL (ppm)
Citrus fruits (Crop Group 10-Revised)	10	10	7.0 (Citrus fruits)
Cucumbers	1.5	1.5	Not Established

Next Steps

The PMRA invites the public to submit written comments on the proposed MRLs for pyrimethanil up to 75 days from the date of publication of this document. Please forward your comments to Publications (see the contact information on the cover page of this document). The PMRA will consider all comments received before making a final decision on the proposed MRLs. Comments received will be addressed in a separate document linked to this PMRL. The established MRLs will be legally in effect as of the date that they are entered into the Maximum Residue Limit Database.

¹ The Codex Alimentarius Commission is an international organization under the auspices of the United Nations that develops international food standards, including MRLs.

Appendix I

Summary of Field and Greenhouse Trial Data Used to Support the Proposed Maximum Residue Limits

Residue data for pyrimethanil in greenhouse cucumbers were submitted to support the domestic use of SCALA[®] SC Greenhouse Fungicide on greenhouse cucumbers. Residue data for pyrimethanil in lemons were submitted to support the maximum residue limit on imported crops included in the lemon/lime Subgroup (Crop Subgroup 10B). Previously reviewed residue data from post-harvest trials conducted in/on citrus fruits were also reassessed in the framework of this petition. In addition, a processing study in treated oranges was reassessed to determine the potential for concentration of residues of pyrimethanil into processed commodities.

Maximum Residue Limits

The recommendation for maximum residue limits (MRLs) for pyrimethanil was based upon the submitted field and greenhouse trial data, and the guidance provided in the OECD MRL Calculator. Table A1 summarizes the residue data used to calculate the proposed MRLs.

Table A1 Summary of Field Trial and Processing Data Used to Support MRLs

Commodity	Application Method/ Total Application Rate	Preharvest Interval (days)	Lowest Average Field Trial Residues (ppm)	Highest Average Field Trial Residues (ppm)	Experimental Processing Factor
Greenhouse cucumbers	Foliar/ 2400-2500 g a.i./ha ¹	1	0.07	0.82	N/A
Lemons	Foliar/ 773-916 g a.i./ha ¹	7	0.11	0.27	N/A
Lemons	Post-harvest/ 1000-5000 ppm	N/A	1.21	6.23	N/A
Grapefruits	Post-harvest/ 1000-4500 ppm	N/A	0.93	4.22	N/A
Oranges	Post-harvest/ 1000-4500 ppm	N/A	1.08	7.86	20.2x (orange oil)

¹ g a.i./ha = grams of active ingredient per hectare

Following the review of all available data, the MRLs proposed in Table 1 are recommended to cover residues of pyrimethanil. Residues of pyrimethanil at the proposed MRLs will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.